

# Notice of Allowability

Application No.

10/530,875

Examiner

Laura B. Goddard, Ph.D.

Applicant(s)

KREYSCH, HANS-GEORG

Art Unit

1642

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to November 2, 2006.
2. ☒ The allowed claim(s) is/are 33-49 and 54.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

  
SHANON FOLEY  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

### **EXAMINER'S AMENDMENT**

1. The Amendment filed November 2, 2006 in response to the Office Action of July 27, 2006 is acknowledged and has been entered. Previously pending claims 1-32 were canceled. New claims 33-54 are added. New claims 33-49 and 54 are drawn to the elected invention of a bispecific antibody comprising two antigen binding sites wherein the binding sites are MAb425 and MAb225. New claims 50-53 are drawn to methods of treating EGFR-related tumor or tumor metastasis comprising using said bispecific antibody.

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Anthony Zelano on 1/19/2007.

3. The application has been amended as follows:

#### **In the specification:**

Amend at page 1 of the specification before the heading "FIELD OF THE INVENTION":

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This application is the national phase under 35 U.S.C. §371 of PCT/EP03/11165 filed October 9, 2003, ~~which claims benefit of earlier filed European Application with the Ser. Nos. 02022389.7, filed October 10, 2002 and 02022390.5, filed October 10, 2002, which are incorporated herein by reference in their entirety.~~

**In the claims:**

**Claim 33:** "...wherein said first antigen-binding site ~~derives from~~ is humanized, chimeric, or murine MAb425 and said second antigen-binding site ~~derives from~~ is humanized, chimeric, or murine MAb225, ...".

**Claim 37:** "A bispecific antibody fragment of claim 33 ~~deriving from the bispecific antibody of claim 1~~, wherein the fragment is F(ab')<sub>2</sub>."

**Claims 50-53** are canceled.

**Reasons for Allowance**

4. The following is an examiner's statement of reasons for allowance: No deposit for antibodies MAb425 or MAb225 were made in the instant application, however, the instant application discloses US Patent 5,558,864 (p. 4, line 18) which teaches the sequences for the variable heavy and light chains of MAb425 and the instant application also discloses US Patent 4,943,533 (p. 4, line 19) which teaches the ATCC deposit number for MAb225 as HB-8508. A search of deposit HB-8508 reveals murine MAb225

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publicly for sale from ATCC (see "ATCC:Cell Biology Collection", p. 1-2). The instant application also discloses the product name Cetuximab (p. 4, line 20) for MAb225 which is the chimeric humanized version of MAb225 sold as "ERBITUX" for the treatment of head and neck cancer (see ImClone, "ERBITUX", p. 1-2). The written description requirements for the monoclonal antibodies of the instant claims has been satisfied.

The amendment to the specification filed November 2, 2006, has been amended to delete the phrase "which are incorporated herein by reference in their entirety" because the statement is improper. MPEP 201.06(c) states: An incorporation by reference statement added after an application's filing date is not effective because no new matter can be added to an application after its filing date (see 35 U.S.C. 132(a)). If an incorporation by reference statement is included in an amendment to the specification to add a benefit claim under 35 U.S.C. 120 after the filing date of the application, the amendment would not be proper. When a benefit claim under 35 U.S.C. 120 is submitted after the filing of an application, the reference to the prior application cannot include an incorporation by reference statement of the prior application. See *Dart Indus. v. Banner*, 636 F.2d 684, 207 USPQ 273 (C.A.D.C.1980). Further, the amendment to the specification filed November 2, 2006, has been amended to delete the claims of benefit to European Application because there is no priority claimed to these applications on the Oath submitted 4/11/2005 and there is no Application Data Sheet stating priority to the European Applications (see MPEP CRF 37 § 1.63(c)).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

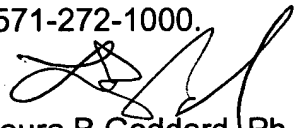
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accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

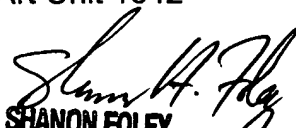
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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